RADx Underserved Populations (RADx-UP)

Advisory Committee to the Director (ACD) Meeting

Monica Webb Hooper, PhD Deputy Director, National Institute on Minority Health and Health Disparities

December 10th, 2021

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RADx-UP Components

Testing

- ✓ Increase testing access and uptake of COVID-19 diagnostic testing
- ✓ Understand and address disparities associated with COVID-19 diagnostic testing

Social, Ethical & Behavioral Implications (SEBI)

- ✓ Assess ethical, structural, social, behavioral, environ-mental, and contextual factors around COVID-19 testing
- ✓ Investigate multilevel testing barriers, cultural beliefs, expectations, mistrust, and communication preferences

Return to School

- ✓ Implement specific, targeted testing approaches in educational settings serving underserved and vulnerable children and their families
- ✓ Identify scalable, and sustainable testing implementation strategies to maintain in-person learning

RADx-UP Strategies

- **Expand capacity to test broadly** for SARS-CoV-2 in underserved and vulnerable populations, including asymptomatic persons, with FDA emergency use authorized or approved tests
- **Inform implementation of mitigation strategies** based on isolation, testing, and contact tracing to supplement mask wearing and physical distancing to limit community transmission and maximize implementation of vaccines
- **Understand factors** that contribute to COVID-19 disparities and **implement interventions** to reduce these disparities
- **Deploy surveys with common data elements** that will be applied across all RADx projects plus additional survey items that are defined for RADx-UP consortium
- **Establish research and data infrastructure** that to facilitate data sharing and current and future research questions

RADx-UP Phase II Snapshot

In FY 2021, Phase II launched funding opportunities for existing NIH grantees and new opportunities open to all investigators

FUNDING OPPORTUNITIES AND AWARDS

6

Funding Opportunity Announcements

Receipt dates:
Return to School: April/May
Vax Hes Supps/Testing CRs: May
SEBI/Testing U01s: July

16

Return to School Program Projects

Two rounds of funding for Spring – Fall school year studies

11

Vaccine Hesitancy Supplements

Supplements for Phase I projects to expand studies to address vaccine hesitancy

10

Testing Projects (CRs)

Interventions to increase access and uptake of COVID-19 testing and vaccination to decrease disparities

NEW FUNDING OPPORTUNITIES

13

Testing Projects (U01s)

Interventions to increase access and uptake of COVID-19 testing and vaccination decrease disparities

&

9

SEBI Project (U01s)

Research and interventions to understand and address social, ethical, and behavioral implications (SEBI) of testing and vaccination

PROGRAM EXPANSIONS

59

Projects Added

3

New Populations

Homeless youth, children with IDD, children with medical complexities

RADx-UP Collaboration – NIH Community Engagement Alliance (CEAL) Against COVID-19

Vaccine Hesitancy Supplements; NOT-OD-21-101

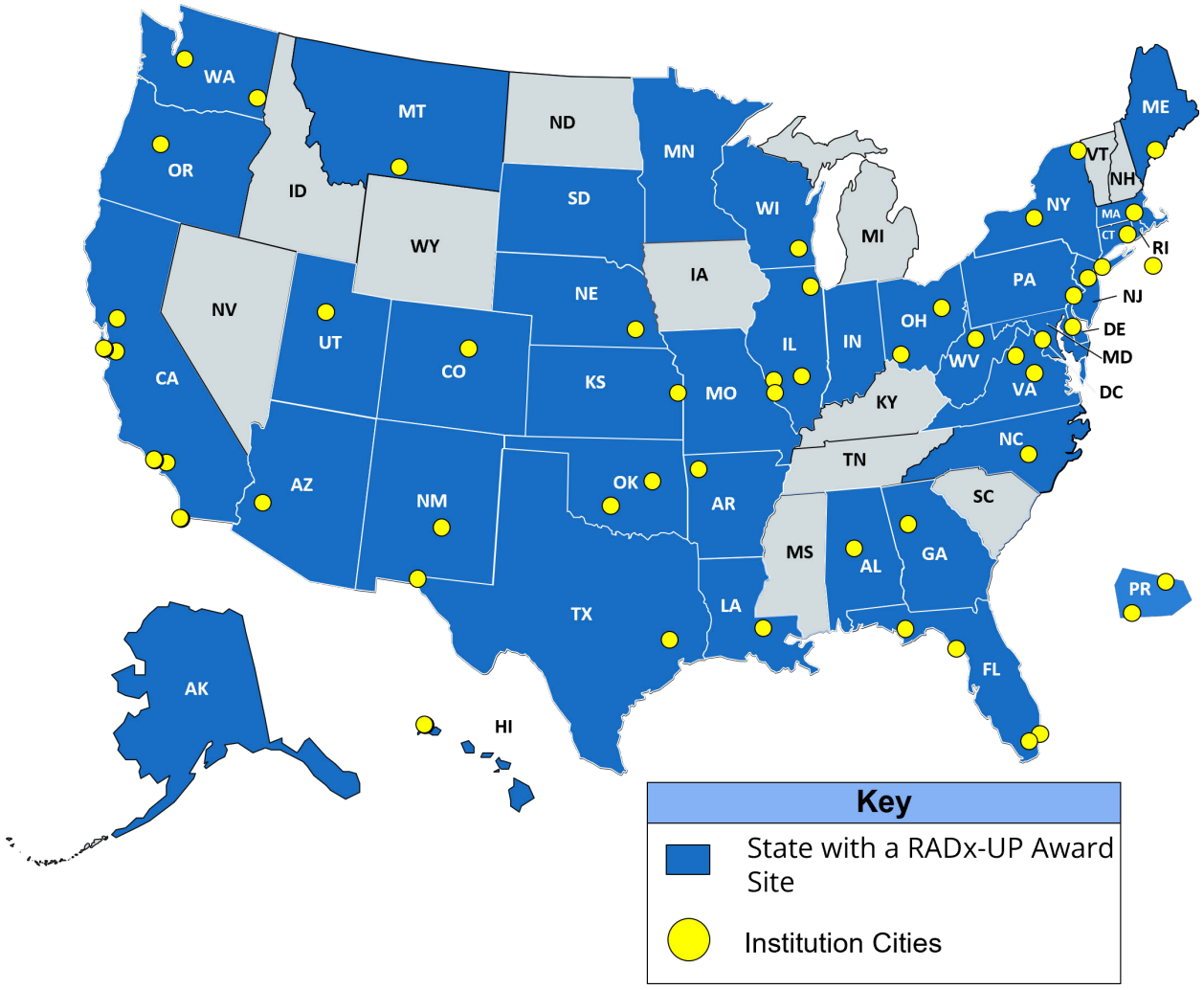
$300,000 in total costs, 1-year projects, 11 awards

- Phase I grantees are conducting brief interventions to address the need to expand outreach and education efforts to **promote testing and foster vaccine confidence, acceptance, and uptake** in underserved and vulnerable communities
- Projects include **strategic collaborations with NIH Community Engagement Alliance Against COVID-19 Disparities (CEAL) research teams** working in the same geographic areas and/or with the same populations, leveraging the other's existing resources to build a robust network

Supported Projects:

- Apply culturally congruent models to address testing and vaccine hesitancy and promote uptake
- Incorporate CEAL-developed, evidence-informed communications on vaccines and testing
- Use varied approaches to work in communities and healthcare contexts to convey accurate health information about testing and vaccination
- Apply "teachable moment" concept to encourage COVID-19 vaccination at the point of testing

Communities Served by RADx-UP Projects



NUMBER OF PROJECTS

- 56 Hispanic or Latino/a
- 22 Asian American
- 4 Native Hawaiian
- 50 Black or African American
- 19 American Indian
- 2 Alaska Native
- 33 Older adults
- 18 Pregnant women
- 1 People who are incarcerated
- 32 Children
- 8 Pacific Islander

Self-reported data reflects RADx-UP Phase I and II projects as of 8/1/2021

Note: Some projects are operating in multiple states, or nationwide
Note: RADx-UP Awards include awards made from the following: NOT-OD-20-120, NOT-OD-20-121,NOT-OD-21-103, OTA-21-004 and OTA-21-007

RADx-UP At a Glance

>100
COVID-19 testing and SEBI projects

1
Coordination & Data Collection Center

56
States, Territories and D.C.

>850,000
Participants Enrolled (includes EHR)

>900,000
Tests conducted as of Oct. 2021
(includes prospective & EHR)

55
Projects submitting data to CDCC

23
Community Collaboration Grants

9
Rapid Research Pilot Awards

37
Journal articles
(acknowledged RADx-UP project grant #)

Findings from RADx-UP-Supported Projects

- **Title: Community Testing and SARS-CoV-2 Rates for Latinxs in Baltimore**
  - Main findings: Racial/Ethnic differences in positivity rates (N = 1,786 patients)
    - Latino persons = 31.5%
    - White persons = 3.4%
    - African American/Black persons = 7.6%
    - Other racial/ethnic groups = 5.3%
  - Among Latino persons, positive tests associated with: Spanish as preferred language, younger age, larger household size
  - Importance: Helps identify areas for targeted, community competent and engaged interventions

Bigelow BF, Saxton RE, Flores-Miller A, et al. Community Testing and SARS-CoV-2 Rates for Latinxs in Baltimore. *Am J Prev Med*. 2021;60(6):e281-e286. doi:10.1016/j.amepre.2021.01.005

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Findings from RADx-UP-Supported Projects

- **Title: Factors Associated With US Public Motivation to Use and Distribute COVID-19 Self-tests**
  - Main findings: High motivation to distribute self-test kits (N = 584)
    - Motivated to distribute self-testing to contacts = 90.1%
    - Motivated to self-test if kit received from contact = 86.1%
  - Motivation to *distribute self-tests* associated with: above-average income, college completion
  - Motivation to *use self-test* received from contact associated with: above-average income, Hispanic ethnicity
  - Importance: Secondary distribution of COVID-19 self-tests may increase uptake, detection. Behavioral interventions may help increase motivation for lower SES persons.

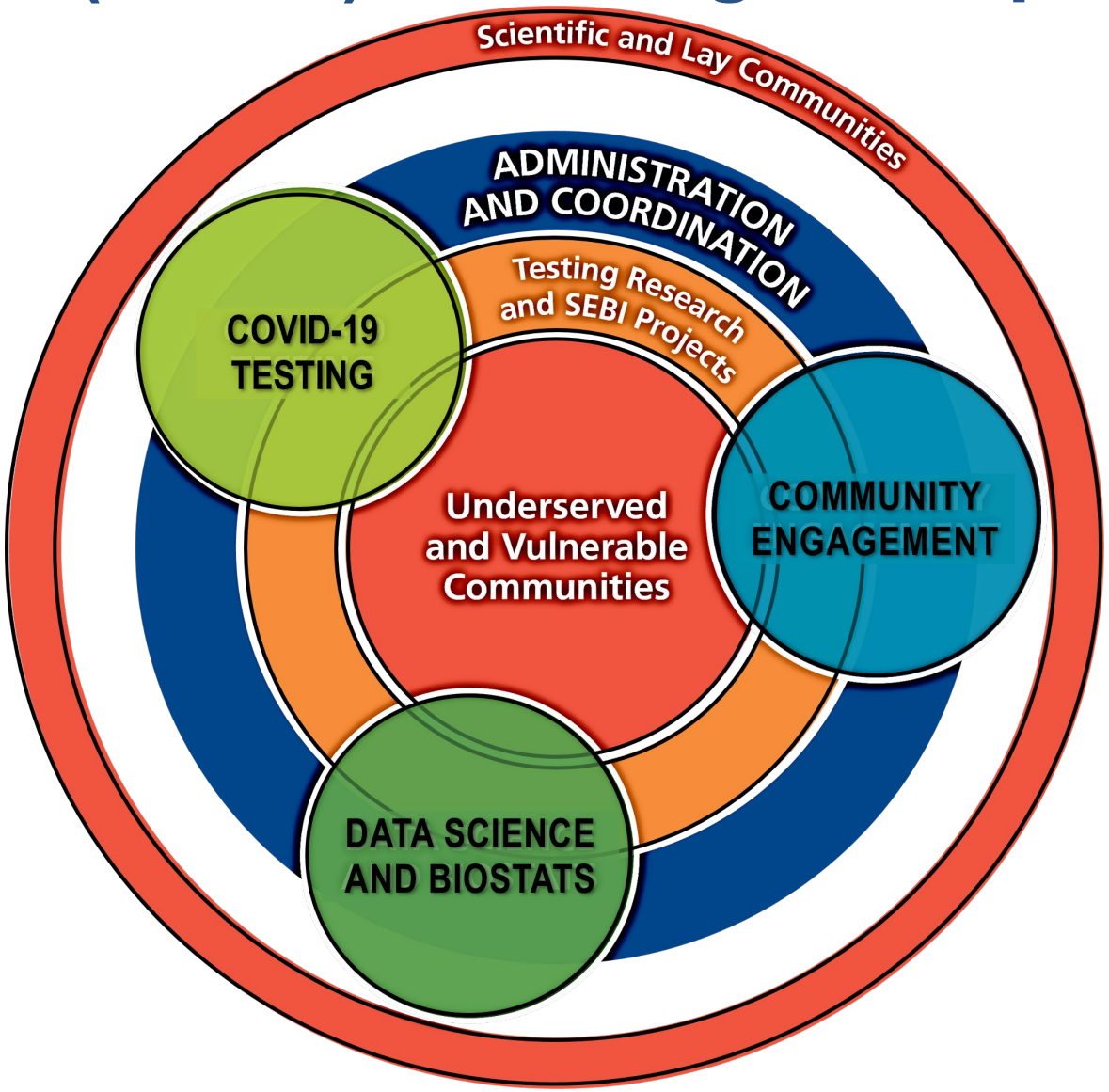
Bien-Gund C, Dugosh K, Acri T, et al. Factors Associated with US Public Motivation to Use and Distribute COVID-19 Self-Tests. *JAMA Netw Open*. 2021;4(1):e2034001. doi:10.1001/jamanetworkopen.2020.34001

Lessons Learned to Date

Phase I RADx-UP Projects

- ✓ For encouraging testing & vaccination, *culturally appropriate education* is important to increase trust in evidence-based sources of COVID-19 information
- ✓ *Community Advisory Boards* have provided key recommendations and support
- ✓ *Community engagement and trust* are essential to ensure the success of COVID-19 testing and vaccination programs
- ✓ *Flexibility and the ability to adapt* is critical
- ✓ *Partnerships* with community health clinics provide a necessary connection to underserved populations

RADx-UP Coordination & Data Collection Center (CDCC) - Guiding Principles



Communities are at the center of our work.

Data sovereignty protections and sharing with communities and participants are essential in building trust and being trustworthy.

Intentional support of study teams is critical to streamline results and troubleshoot.

Broad dissemination of program activities, data, and best practices are key.

Strategic partnerships will augment community benefits from the program.

Impact will be broad and will inform national guidance, strategy, and response to COVID-19.

Return to School

Alison Cernich, Ph.D., Deputy Director, *Eunice Kennedy Shriver* National Institute of Child Health and Human Development

December 10, 2021

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Return to School Diagnostic Testing Initiative

Goals

- Provide evidence for the effectiveness, sustainability, and scalability of COVID-19 testing approaches and mitigation strategies in school settings in underserved and vulnerable communities
- Provide information to understand the social, behavioral, and ethical implications of implementation of COVID-19 testing within identified communities

Mechanism

- Other Transaction Authority to provide flexibility for changing circumstances and eligible organizations (OTA-21-004 and OTA 21-007)

Approach

- Emphasis on children & adolescents not eligible for vaccination via Emergency Use Authorization (<16 years, Phase 1; < 12 years, Phase 2) and all school personnel
- Advance methods to integrate testing in return to or maintenance of in-person instruction

Budget

- $58 million (from the NIH OD congressional appropriation)

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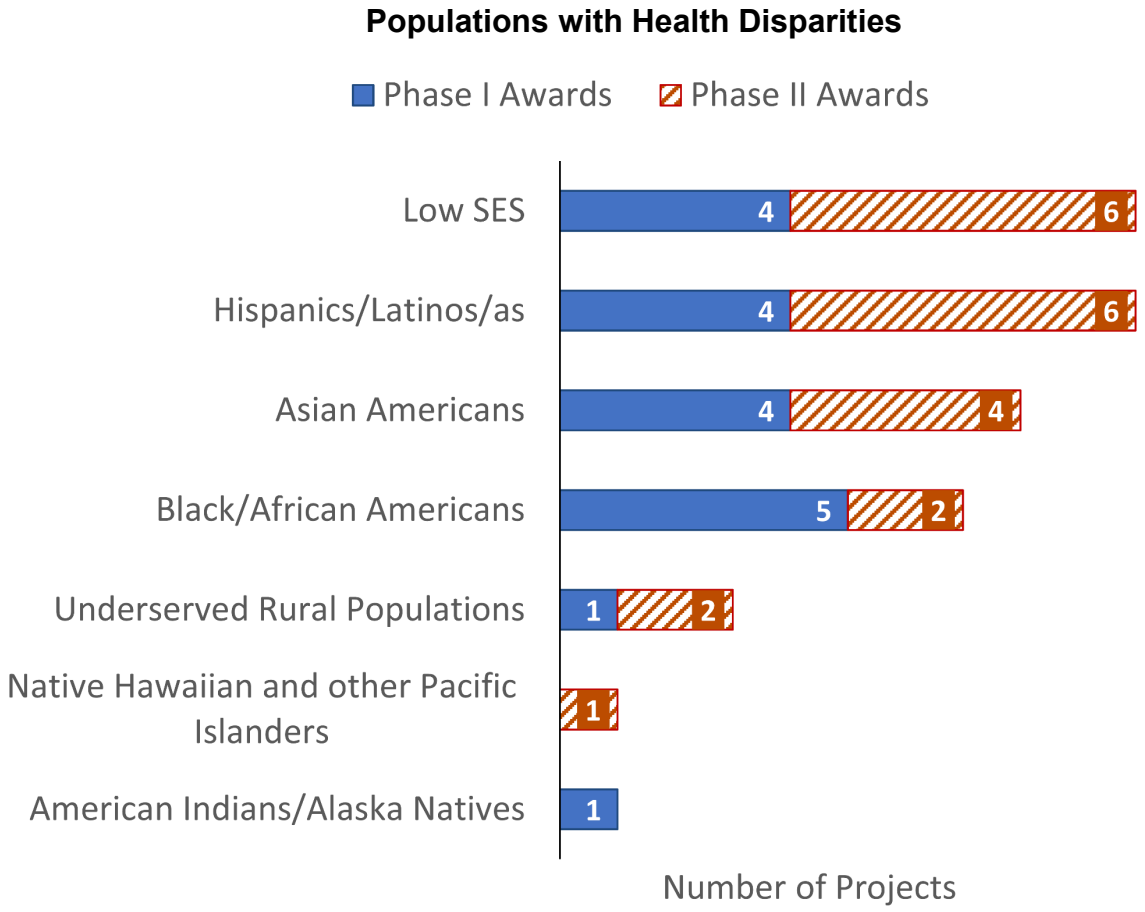
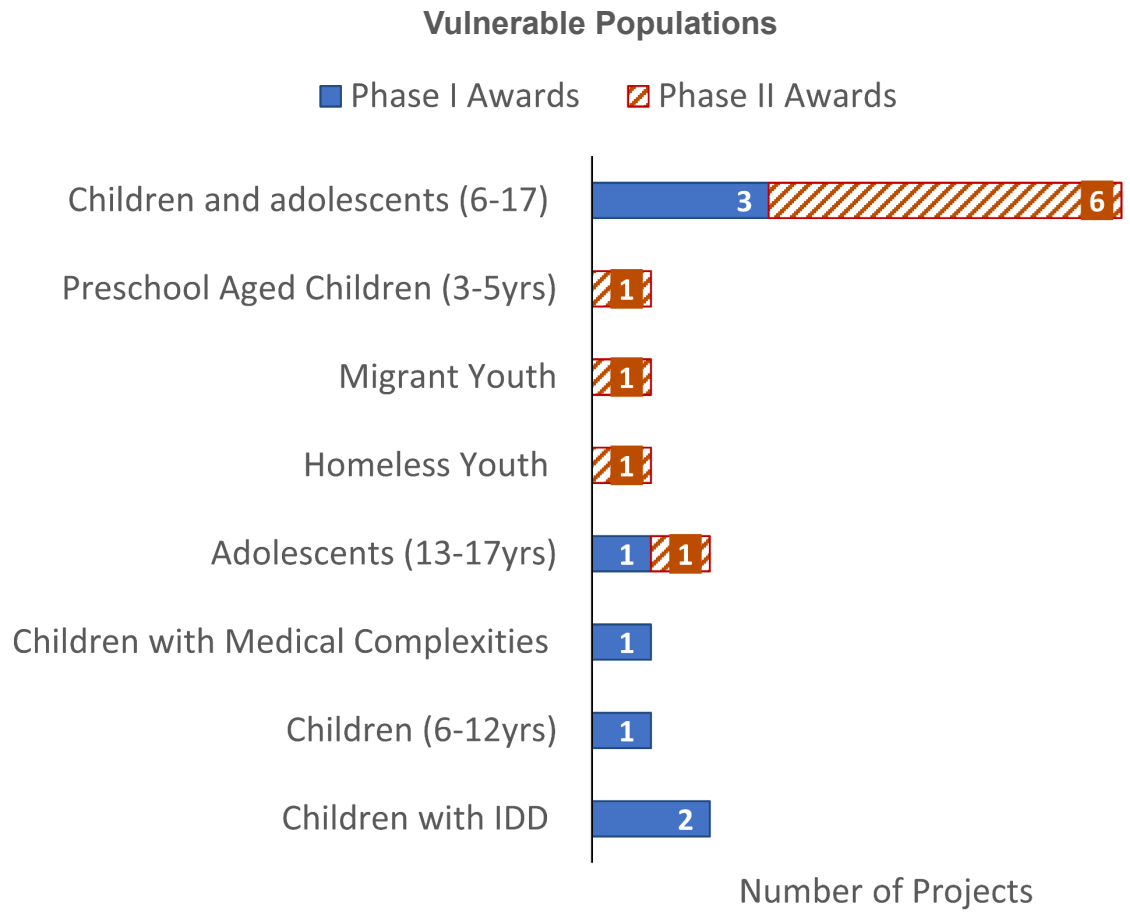
Populations with Health Disparities and COVID-19 Vulnerable Populations





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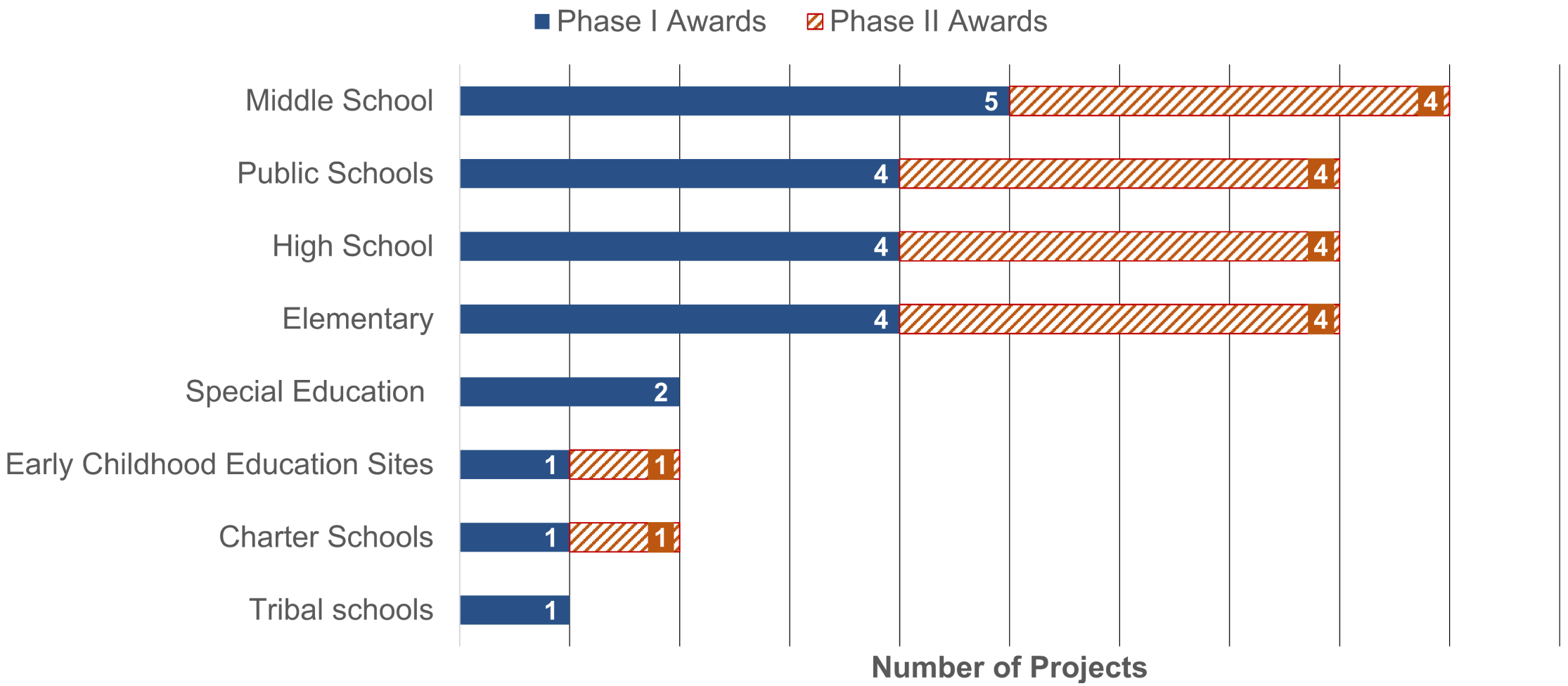
Note: There are projects working with multiple populations; the number of projects is not additive

Educational Settings



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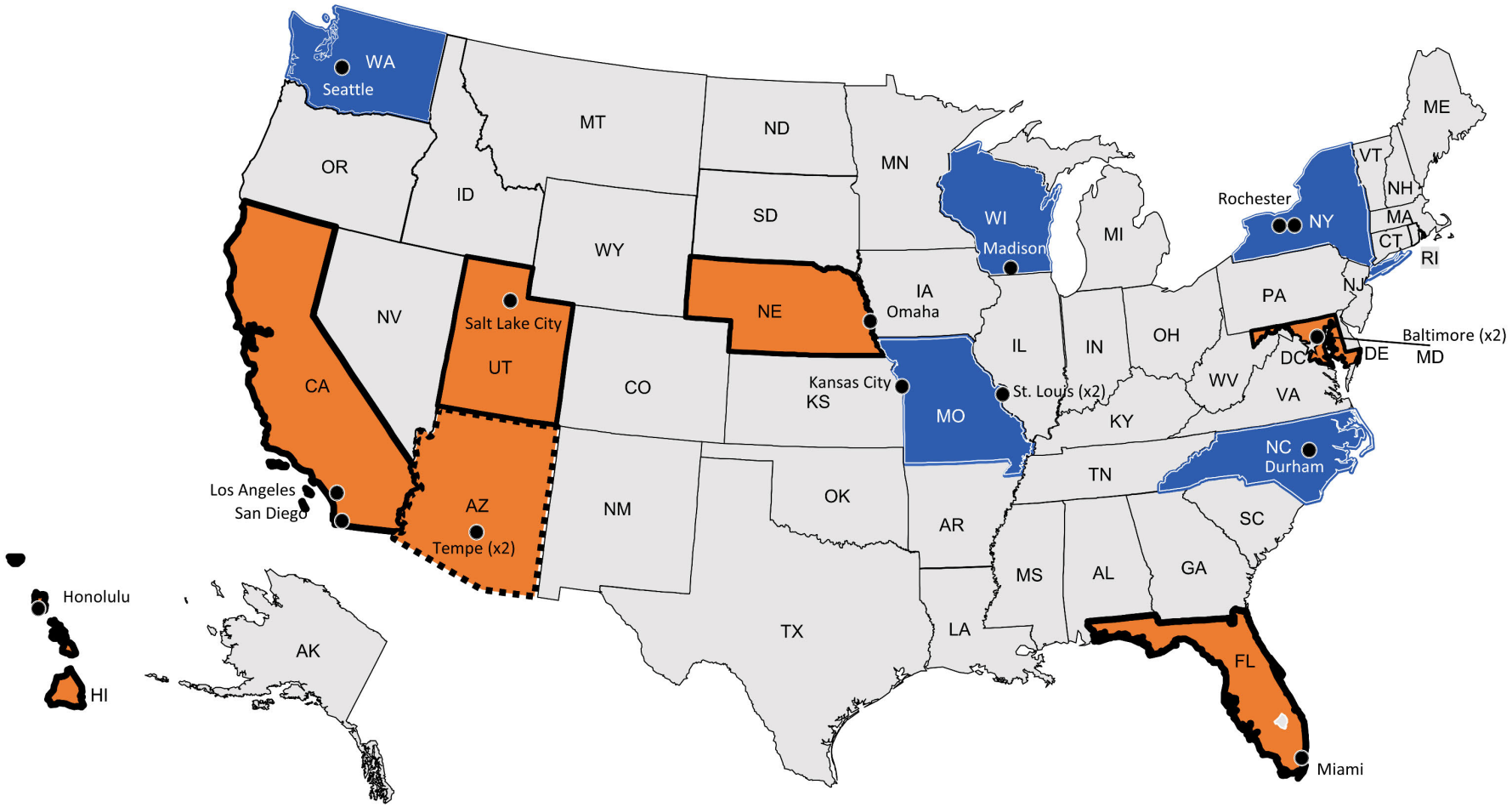
Geographic Distribution of Awarded Projects



Legend

- Phase I Awarded Site
- Phase II Awarded Site
- Phase I & II Awarded Sites
- Award Institution City

Note: 16 projects were awarded across 41 participant sites in 12 states

Note: 600,000 students and at least 75,000 staff, parents, and community members across participant sites

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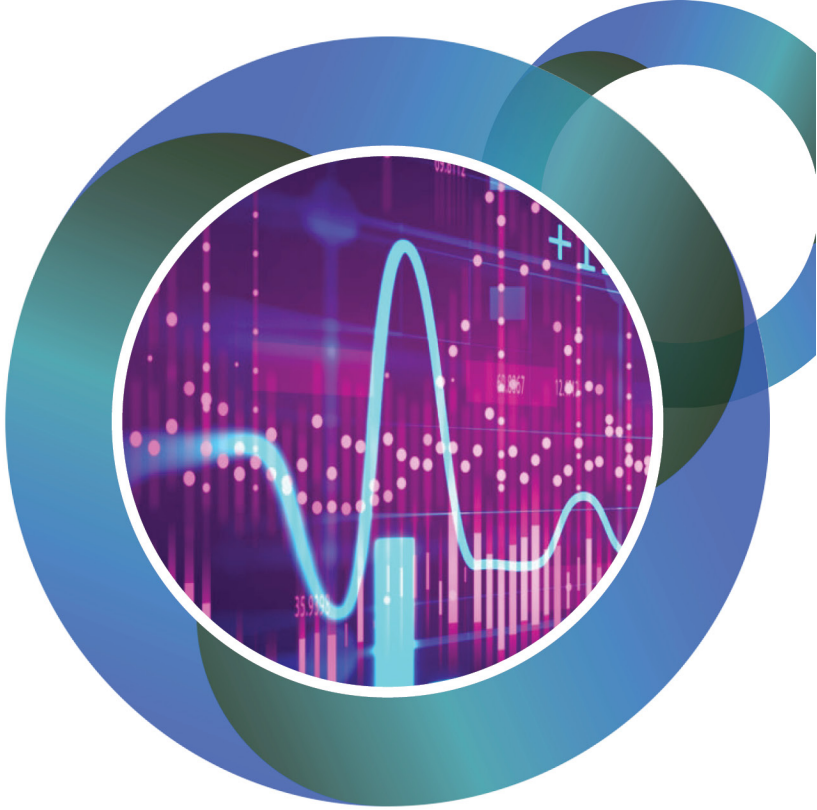
Return to School Preliminary Results



- COVID-19 testing is feasible and acceptable in the school setting across a range of populations and settings
- After implementing a testing program for students and staff after SARS-CoV-2 exposure, there was increased access to testing (37% increase) and the number of days in quarantine for students/staff decreased overall (28% moved from >10 days to <10 days)
- Low rates of within-school transmission were observed with COVID-19 testing and mitigation strategies in place (*data predates Delta variant dominance)
- Both surveillance and post-exposure testing are important strategies to return and keep students in school, especially for those children with disabilities who may not be able to effectively use other mitigation methods
- Preliminary results from Phase I projects recently published in *Pediatrics*

Return to School Lessons Learned

- Framing COVID-19 testing as a school safety measure with other mitigation strategies increases research participation
- Trusted school champions are instrumental in recruiting students and staff for testing
- Communication directly with parents is most effective for increasing testing uptake
- Engagement with communities about the who, what, when, and where, of testing ensures families receive accurate information
- Strong relationships with school nurses and other medical consultants is vital for dissemination of testing results
- Examples from our Phase I projects were shared in a public workshop in August of 2021

Project Safe Schools - Lessons Learned

Implementation Support

- Implementing testing is acceptable and feasible in schools
- Greater success achieved with implementation support from partners and organizations knowledgeable about the culture and community

Multi-Test Approach

- Data to date suggest that surveillance + rapid follow-up testing helps communities feel safer about in-person learning

Spread in Schools

- Re-opening schools does not seem to be a significant driver of SARS-CoV-2 spread

Returning to School

- Roughly 60% of families returning to in-person learning – we are exploring more about this through our qualitative work.

Mental Health

- Additional mental health support is needed; school resources stretched thin and child mental health is a concern is elevated.

PI: Allison Barlow – OT2HD107543

Children with Intellectual and Developmental Disabilities or Medical Complexity – Lessons Learned

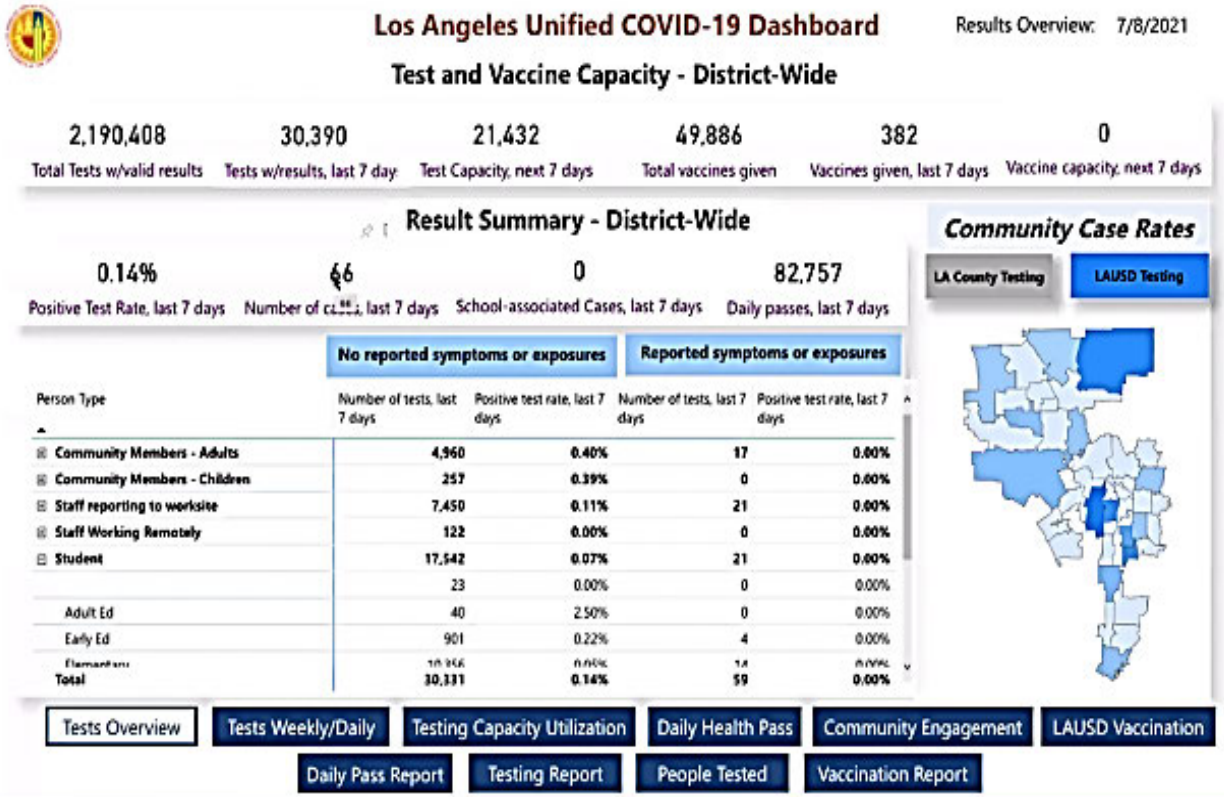
- Demonstrated feasibility of at-home testing for in-home and in-school cohort of children with complex medical conditions including logging testing and adhering to testing schedule
- Identified perceptions of teachers and staff that masking, vaccination, cleaning/disinfecting routines, quarantine protocols, and daily health checks are more highly valued than testing as prevention strategies
- Studying what testing approaches, patterns and frequency are needed to detect asymptomatic cases, minimize risk of transmission, and monitor immunity; includes serology

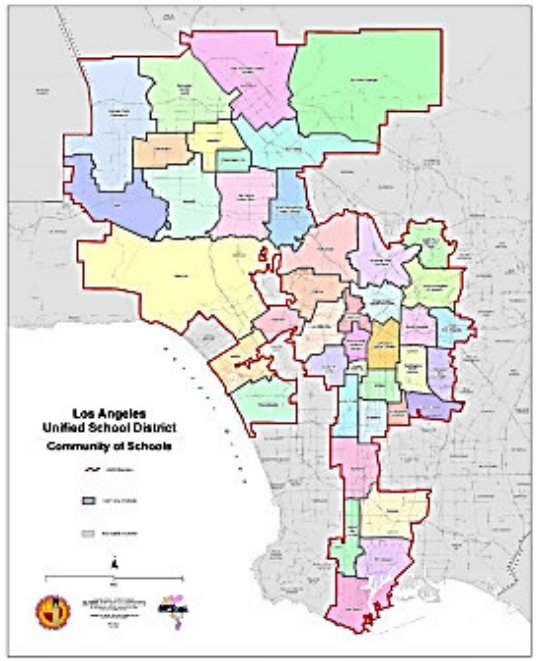
Expected Outcomes Forthcoming

- Effectiveness of COVID-19 testing approaches to reduce onsite school transmission; information on other mitigation strategies
- Data on barriers/facilitators to testing uptake including test preference
- Information on impact of vaccines and vaccine hesitancy
- Models for community engagement and dissemination/implementation of testing results
- Data on impact of testing on rates of school attendance
- Qualitative data on school community perceptions of testing
- Potential to modify projects to include new testing models such as “Test-to-Stay”

COVID-19 Testing & Mitigation Impact: Equitable Return-to-School in the Second Largest U.S. School District

Testing program measures





UCLA

PIs: Moira Inkelas & Mitchell Wong – OT2HD108103

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Maximizing Child Health & Learning Potential during COVID-19 in the Fourth Largest U.S. School District

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of MEDICINE

- Develop and implement COVID-19 testing protocol to return and maintain children who have been exposed to the virus to the in-classroom setting
- Includes a mobile testing strategy with the utilization of a pediatric mobile clinic that travels to underserved neighborhoods and provides comprehensive healthcare services to uninsured children throughout Miami-Dade County
- The County and District do not have testing protocols and other mitigation strategies are inconsistent in this district
- Project includes research on health education and vaccine confidence initiatives

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PIs: Lisa Gwynn, Elizabeth Pulgaron, and Viviana Horigian – OT2HD108111

RADx-UP – Potential Future Directions

* Pending suitable funding

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Key Research Questions

Partnership-driven research to implement and evaluate rapid testing, and prevent and control COVID-19 transmission:

- Use of rapid antigen testing to control transmission in homes, educational settings, workplaces, and other congregate settings. Effects of rapid tests on reporting, contact tracing, and long-term disease control.
- Social, ethical, and behavioral implications of testing, vaccine, and mask mandates and effects on uptake of mitigation behaviors, including ongoing COVID-19 testing and vaccination.
- New models of testing and other strategies, such as sequencing, to help identify and mitigate the transmission of existing or new variants in high density environments.
- Research on the social determinants of health to help identify, understand, and address testing and vaccine access and uptake, as well as effective communication strategies in low-resourced geographic areas.
- Rapid testing and surveillance research to help identify breakthrough infections and minimize transmission of SARS-CoV-2.

Thank you

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